UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Subcategory No. 03-10643
THIS DOCUMENT RELATES TO: *City of New York v. Abbott Labs., et al.* (S.D.N.Y. No. 04-CV-06054) *County of Suffolk v. Abbott Labs., et al.* (E.D.N.Y. No. 03-CV-229) *County of Westchester v. Abbott Labs., et al.* (S.D.N.Y. No. 03-CV-6178) *County of Rockland v. Abbott Labs., et al.* (S.D.N.Y. No. 03-CV-7055) *County of Dutchess v. Abbott Labs., et al.* (S.D.N.Y. No. 05-CV-06458) *County of Putnam v. Abbott Labs., et al.* (S.D.N.Y. No. 05-CV-04740) *County of Washington v. Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00408) *County of Rensselaer v. Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00422) *County of Albany v. Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00425)	Judge Patti B. Saris

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LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS SUPPORTING DEFENDANTS' JOINT MOTION FOR SUMMARY JUDGMENT ON PLAINTIFFS' "FUL FRAUD" CLAIMS

County of Warren v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00468))
County of Greene v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00474))
County of Saratoga v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00478))
County of Columbia v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00867))
Essex County v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00878))
County of Chenango v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00354))
County of Broome v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00456))
County of Onondaga v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00088))
County of Tompkins v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00397))
County of Cayuga v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00423))
County of Madison v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00714))
County of Cortland v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00881))
County of Herkimer v. Abbott Labs. et al.)
(N.D.N.Y. No. 05-CV-00415))
County of Oneida v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00489))
County of Fulton v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00519))
County of St. Lawrence v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00479))
County of Jefferson v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00715))
County of Lewis v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00839))
County of Chautauqua v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06204))
County of Allegany v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06231))
County of Cattaraugus v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06242))

County of Genesee v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06206))
County of Wayne v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06138))
County of Monroe v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06148))
County of Yates v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06172))
County of Niagara v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06296))
County of Seneca v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06370))
County of Orleans v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06371))
County of Ontario v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06373))
County of Schuyler v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06387))
County of Steuben v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06223))
County of Chemung v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06744))
AND)
County of Nassau v. Abbott Labs., et al.)
(E.D.N.Y. No. 04-CV-5126))
_____)

Pursuant to Local Rule 56.1, defendants present this statement of material facts as to which there is no genuine issue to be tried in support of their Joint Motion for Summary Judgment on Plaintiffs' "FUL Fraud" Claims.

1. The national pricing compendia publish Average Wholesale Prices, Wholesale Acquisition Costs, and Direct Prices. Transcript of Deposition of Sue Gaston ("Gaston Tr.") at 145:5 – 145:10, attached to the Declaration of Kim B. Nemirow (hereinafter "Nemirow Decl.") as Ex. A.

2. A product is considered "therapeutically equivalent" if it is "A-rated" by the Food and Drug Administration ("FDA") in its publication, *Approved Drug Products with*

Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." 42 C.F.R. § 447.332(a)(ii).

3. CMS was free to update FULs periodically and did so at its discretion. Nemirow Decl. Ex. A (Gaston Tr. at 530:3 – 530:13).

4. In formal transmittals by which CMS communicated FULs to State Medicaid programs, CMS identified the dates of the published prices on which it had relied when setting the FULs. Affidavit of Dr. Sumanth Addanki ("Addanki Aff."), at ¶ 10.

5. In Case Management Order No. 33, the Court directed each side to select five drugs that were reimbursed by New York Medicaid on the basis of FULs for "targeted" discovery. *See* CMO 33, *In re Pharm. Indus. Avg. Wholesale Price Litig.*, No. 01-CV-12257-PBS, MDL No. 1456 (D. Mass. Sept. 14, 2007) [Docket No. 4745]. Because both sides chose enalapril maleate, there were nine drugs, identified by the Generic Code Number or GCN, assigned by First Databank to a "therapeutically equivalent" group of drugs, that became of the subject of the targeted FUL discovery: (1) albuterol 0.083% solution (GCN 5309); (2) albuterol 90 mcg. inhaler (GCN 5037); (3) cefadroxil 500 mg. (GCN 9089/48268); (4) clonazepam 0.5 mg. tablet (GCN 4560); (5) enalapril maleate 20 mg. tablet (GCN 386); (6) isosorbide mononitrate 60 mg. tablet SA (GCN 17927); (7) lorazepam 1 mg. tablet (GCN 3758); (8) metroprolol tartrate 100 mg. tablet (GCN 5131); and (9) ranitidine 150 mg. tablet (GCN 11673). *See* Addanki Aff., at ¶ 9.

The Empirical Evidence

6. For the nine GCNs or drugs that were the subject of the targeted FUL discovery, between 1997 and 2005 (the discovery period specified by the Court in CMO 33), CMS established 31 different FULs. *See id.* at ¶ 8 & Exs. 3-5.

7. Of the 31 FULs that CMS established for the target drugs during the relevant time, CMS would have established a lower FUL in 23 out of 31 cases (nearly 75% of the time) had CMS followed the rule set forth in the FUL regulation – *i.e.*, had CMS established the FUL by multiplying the lowest available published price by 150%. *Id.* at ¶ 11 & Ex. 3.

8. For all but two of the FULs at issue here (*i.e.*, for 29 out of 31 FULs), during the period for which the FUL remained in effect, there existed at least one published price that, if used, would have resulted in a lower FUL for some portion of, and many times the entire period for which the FUL remained in effect. *Id.* at ¶ 12 & Ex. 4.

9. For 25 out of the 31 FULs at issue here, during the period in which the FUL was in effect, there was ***always*** a lower published price in effect upon which a lower FUL could have been set. *Id.* (emphasis in original). In at least two instances, a lower price was published between the date the FUL was set by CMS and the date the FUL became effective.

10. For 25 out of the 31 FULs that were the subject of the targeted discovery, a different FUL would have resulted if CMS had complied with all of the regulatory requirements. *Id.* at ¶ 8 & Ex. 3.

11. Dr. Addanki was unable to discern any pattern in CMS's departure from the regulatory requirements when establishing FULs. *Id.* at ¶¶ 8, 19.

The CMS Testimony

12. Sue Gaston was the CMS employee responsible for setting FULs from April 1991 through February of 2003. Nemirow Decl. Ex. A (Gaston Tr. at 40:7 – 40:10, 45:2 – 45:12).

13. Gail Sexton was the CMS employee responsible for setting FULs beginning in 2004. Transcript of Deposition of Gail Sexton ("Sexton Tr.") at 49:13 – 50:21, attached to Nemirow Decl. as Ex. B.

14. Ms. Sexton testified that the nine drugs that were selected for targeted FUL discovery, and which formed the basis for Dr. Addanki's study, are not unique, and that the process used to set the FULs for these drugs is representative of the process for establishing FULs more generally. Nemirow Decl. Ex. B (Sexton Tr. at 31:4 – 31:22, 33:1 – 33:9).

15. Ms. Gaston and Ms. Sexton testified that CMS used a computer program ("the FULs System") to gather both Orange Book data and pricing data from the three national compendia and to initially calculate FULs for those drugs that met the specified criteria. Then, CMS officials would engage in a "manual review" process because "we want to be sure that that lowest price is a true price." Nemirow Decl. Ex. A (Gaston Tr. at 232:22 – 241:7, 410:14 – 411:18, 416:10 – 416:15, 429:18 – 429:22, 432:14 – 432:21, 533:5 – 533:10); Nemirow Decl. Ex. B (Sexton Tr. at 89:2 – 89:5, 93:13 – 94:13) (stating that Ms. Sexton conducted "further manual interventions" into the FUL for albuterol because she had "learned of other suppliers that were marketing this drug"); *id.* at 95:15 – 95:20 (stating that she would conduct a manual review "in cases where I saw that manual intervention could have changed the price, changed the federal upper limit, or where it appeared that perhaps the criteria was not met and that further intervention should have been taken"); *id.* at 138:6 – 138:7 ("When possible we would manually verify that drugs were available."); *id.* at 147:8 – 147:15 (stating that upon finding "an outlier situation" she would "do some manual verifications on whether that NDC was available and available at that price").

16. Ms. Gaston further testified that the manual review was used to determine whether a drug was "truly available or not" and whether or not "you should follow up and see if it's available." Nemirow Decl. Ex. A (Gaston Tr. at 229:8 – 230:14).

17. During her deposition, Ms. Gaston was presented with the 2001 FULs System printout for clonazepam, on which someone had crossed out the FUL generated by the FULs System, $0.1199, and written in a different, higher FUL, $0.2455. Nemirow Decl. Ex. A (Gaston Tr. at 441:22 – 442:5 & Ex. 5).

18. Ms. Gaston testified that the lowest published price was not used when setting the FUL for clonazepam because CMS "wanted to make sure that the FUL price that's set is a reasonable price and that we'll be assured the availability of the drug" and that therefore "we went up to the next lowest price." Nemirow Decl. Ex. A (Gaston Tr. at 442:21 – 445:13).

19. During her deposition, Ms. Gaston was presented with the 2001 FULs System printout for lorazepam, on which someone had crossed out the FUL generated by the FULs System, $0.2999, and written in a different, higher FUL, $0.5718. Nemirow Decl. Ex. A (Gaston Tr. at 445:1 – 445:10 & Ex. 6).

20. Ms. Gaston testified that CMS used a price other than the lowest published price for lorazepam as the basis for the FUL to ensure that the FUL was set at a "reasonable" level. Nemirow Decl. Ex. A (Gaston Tr. at 446:1 – 446:10, 450:6 – 453:1).

21. During her deposition, Ms. Gaston was presented with the 2001 FULs System printout for cefadroxil, on which someone had crossed out the FUL generated by the FULs System, $1.2749, and written in a different, higher FUL, $2.9000. Nemirow Decl. Ex. A (Gaston Tr. at 453:12 – 453:15 & Ex. 7).

22. Ms. Gaston testified that the FUL for cefadroxil that had been calculated by the FULs System required "some manual review" because the price on which it had been based "seemed much lower than all the other published prices." Nemirow Decl. Ex. A (Gaston Tr. at 455:6 – 455:12)

23. During her deposition, Ms. Gaston was presented with the 2001 FULs System printout for metoprolol tartrate, which showed a FUL generated by the FULs System of $0.0816 and a handwritten notation that the "new FUL" was $0.0914. Nemirow Decl. Ex. A (Gaston Tr. at 419:18 – 419:22 & Ex. 2).

24. Ms. Gaston testified that CMS did not use a lower published price to calculate the FUL for metroprolol tartrate because it had discovered that the manufacturer that had reported that lower price was "temporarily out of stock" and that a FUL resulting from that price "might not be a realistic price." Nemirow Decl. Ex. A (Gaston Tr. at 425:15 – 427:20).

25. Ms. Sexton testified that, in February of 2005, the FULs System calculated a FUL for lorazepam, one of the drugs at issue, based on a published price of $0.077, but that Ms. Sexton chose not to change the previous FUL, which had been based on a published price of $0.3812. Nemirow Decl. Ex. B (Sexton Tr. at 126:14 – 128:11).

26. Ms. Gaston testified that when she was setting FULs, she would base FULs on B-rated drugs, rather than A-rated drugs, as long as three A-rated drugs were listed in the Orange Book. Nemirow Decl. Ex. A (Gaston Tr. at 523:15 – 524:11, 525:8 – 525:13).

27. Ms. Sexton testified that, when she set a FUL for a particular drug, she would consider drugs that were not listed as A-rated in the Orange Book, and set the FUL according to that price. Nemirow Decl. Ex. B (Sexton Tr. at 104:13 – 104:18) (regarding the FUL for the 90 mcg. albuterol inhaler).

28. Ms. Gaston testified that when CMS set the FUL for cefadroxil, one of the subject drugs, the FUL was not based on the most common package size. Nemirow Decl. Ex. A (Gaston Tr. at 466:19 – 469:14) (recognizing that while the most common package size was found to be the 100-count of cefadroxil, the FUL had been set on the 50-count package size).

29. Ms. Sexton testified that, when she set the FUL for isosorbide mononitrate, she called the manufacturer to determine their unpublished WAC price and set the FUL according to that information. Nemirow Decl. Ex. B (Sexton Tr. at 113:20 – 113:21, 117:12 – 118:3).

30. Dr. Addanki found that the FUL for cefadroxil between January 1, 1997 and August 31, 1998 was based on an out-of-date price. Addanki Aff., at ¶ 11 n.5.

31. Ms. Gaston testified that CMS removed the FUL for the 90 MCG albuterol inhaler upon learning of a shortage of the drug's raw material because "if the product is not available, then it wouldn't make sense to put a FUL price on it." Nemirow Decl. Ex. A (Gaston Tr. at 470:7 – 472:21).

32. Similarly, CMS removed FULs for the .083% albuterol solution and lorazepam during the period at issue. *See* Addanki Aff., at Ex. 3.

33. Ms. Gaston testified that CMS officials would not use a particular published price if that manufacturer "only distribute[d] to maybe [a] limited amount of states and not all states." Nemirow Decl. Ex. A (Gaston Tr. at 429:9 – 429:17).

34. CMS officials would decline to set a FUL when the FUL was equal to an AWP because States' "regular reimbursement methodology would be a percentage off of AWP," such that setting a FUL that was equal to AWP "would kind of counter what the states were doing with their other reimbursement methodology." Nemirow Decl. Ex. A (Gaston Tr. at 456:10 – 456:20) (discussing the FUL for cefadroxil); *see also* Nemirow Decl. Ex. B (Sexton Tr. at 76:20

– 77:13) (stating that she could not recall ever having set a FUL based on an AWP). Ms. Gaston testified that CMS "wouldn't have used AWP" when establishing FULs because "[s]etting a FUL using the AWP wouldn't achieve the cost savings." Nemirow Decl. Ex. A (Gaston Tr. at 458:15 – 459:7); *see also* Nemirow Decl. Ex. B (Sexton Tr. at 58:15 – 59:8) ("[I]f the federal upper limit, once it was calculated, was higher than the AWP price or the majority of the AWP prices, then we would generally not set a FUL on those drug ingredients, because the AWP—well, a couple years ago the average AWP on a national basis was I think AWP minus 12 percent for drug reimbursement, estimated acquisition costs for drug reimbursement for a drug that did not have a federal upper limit.").

35. CMS did not have any written policy in place for employees to follow in setting FULs, and CMS officials individually made decisions about whether and at what rate to set a FUL on a case-by-case basis. Nemirow Decl. Ex. A (Gaston Tr. at 250:2 – 250:6, 252:3 – 252:6, 464:7 – 465:16); Nemirow Decl. Ex. B (Sexton Tr. at 60:22 – 61:7).

36. CMS officials were informally taught by other CMS officials how to exercise their discretion to set FULs manually so as to meet the dual objectives of cost savings and access. Nemirow Decl. Ex. A (Gaston Tr. at 225:16 – 226:7); Nemirow Decl. Ex. B (Sexton Tr. at 73:14 – 74:22).

CMS's Objectives When Setting FULs

37. When asked about CMS's objectives when establishing FULs, Sue Gaston testified as follows:

> Q. So what we see in Exhibit 6 is another situation in which, exercising its discretion, CMS chose to set a FUL not based on the lowest published price but based on the next lowest published price because that's what was reasonable to do in terms of ensuring access, correct?
>
> A. Correct.

Nemirow Decl. Ex. A (Gaston Tr. at 451:12 – 451:19).

38. In summary, Ms. Gaston further testified as follows:

> Q. So as we've kind of seen throughout, CMS is trying to establish a FUL that's not too low and not too high to achieve a cost savings, but also not set it too low to create an access issue; that's the balance CMS is trying to strike?
>
> A. Correct.
>
> Q. And you did that—the balance was struck, sometimes the computer program worked as it was supposed to and that balance was struck by the computer program, but other times it was the result of manual intervention?
>
> A. Correct.
>
> Q. And the manual intervention resulted in CMS making a choice in its discretion, correct?
>
> A. Correct.

Nemirow Decl. Ex. A (Gaston Tr. at 498:16 – 499:9).

CMS's Investigations into Market Conditions

39. Ms. Gaston testified that she had access to the AMP information that manufacturers reported to CMS. Nemirow Decl. Ex. A (Gaston Dep. at 528:1 – 528:3) ("Q. Would you have had access to that AMP information? A. Yes.").

40. CMS officials received feedback from members of the pharmacy community and from State Medicaid agencies about "whether they felt that the FUL prices or the drugs were correctly on the FUL list or needed [to be] adjust[ed]"; whether the product was "available"; and whether "the pricing appears to be either too low or too high." Nemirow Decl. Ex. A (Gaston Tr. at 433:14 – 434:8, 435:8 – 435:11); *see also* Nemirow Decl. Ex. B (Sexton Tr. at 110:14 – 110:21) (stating that in addition to feedback from industry groups, she received feedback "from pharmacy providers or states").

41. In response to feedback that a drug was not available, CMS officials would "call the manufacturer or wholesaler and verify if that was a fact." Nemirow Decl. Ex. A (Gaston Tr. at 435:12 – 435:21); *see also* Nemirow Decl. Ex. B (Sexton Tr. at 111:12 – 111:17) (stating that in response to feedback, Ms. Sexton "would look at the availability in the compendia" or "call suppliers").

42. CMS officials telephoned drug manufacturers, wholesalers, or a compendia publisher when the databases did not provide the WAC for a particular NDC or to determine whether a drug was available. Nemirow Decl. Ex. B (Sexton Tr. at 60:22 – 61:20) ("There were times when we would call or I would call the manufacturer or the suppliers to determine if a drug was available. . . . [S]ome of these drugs were looked at, most of them, on a case-by-case basis because there were times when we would have three or more suppliers but perhaps we were missing a wholesale acquisition cost, for instance."); *id.* ("[I]f you just looked at the prices that were on the pricing sheet and there was a wholesale acquisition cost that was missing, that could have had a lower wholesale acquisition cost than the prices that were shown . . . ."); *id.* at 116:1 – 116:14 ("So to determine whether there was a lower WAC out there, that looks like that was the impetus for the calls.").

43. Ms. Gaston testified that she would sometimes review state MAC prices to "verify that the FUL price that we establish is in the ballpark" and "looks realistic for states." Nemirow Decl. Ex. A (Gaston Tr. at 478:17 – 479:9).

The Deficit Reduction Act of 2005

44. In 2006, Congress passed the Deficit Reduction Act ("DRA"), which amended the FUL statute, 42 U.S.C. § 1396r-8, so as to require CMS to "substitute 250 percent of the average manufacturer price (as computed without regard to customary prompt pay discounts

extended to wholesalers) for 150 percent of the published price." Pub. L. No. 109-171, § 6001, 120 Stat. 4, 54-55 (2006).

45. Congress changed the formula for calculating FULs "[i]n an effort to lower inflated Federal upper limit amounts and bring Medicaid reimbursement for generic drugs more in line with actual costs." Dep't of Health & Human Servs., Office of Inspector Gen., *Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program* 10 (June 2007) (OEI-03-06-00400), *available at* http://www.oig.hhs.gov/oei/reports/oei-03-06-00400.pdf; *see also* Congressional Budget Office, *Cost Estimate: S. 1932: Deficit Reduction Act of 2005*, at 37 (Jan. 27, 2006), *available at* http://www.cbo.gov/ftpdocs/70xx/doc7028/s1932conf.pdf.

46. The Congressional Budget Office estimated that calculating FULs as 250% of AMP would "reduce Medicaid spending by $3.6 billion over the 2006–2010 period and $11.8 billion over the 2006–2015 period." *Id.*

47. In December 2006, the Government Accountability Office ("GAO") sent Congress the results of a study the GAO had conducted comparing FULs calculated using the new formula established by the DRA, with retail pharmacy acquisition costs. Gov't Accountability Office, *Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs* (Dec. 22, 2006) (GAO-07-239R), *available at* http://www.gao.gov/new.items/d07239r.pdf. The GAO found that "[t]he AMP-based FULs [it] estimated using AMP data from first quarter 2006 were lower than average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs in [its] sample." *Id.* at 4.

48. The GAO further determined that "[f]or [its] entire sample of 77 multiple-source outpatient prescription drugs . . . these estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for the first quarter of 2006." *Id.*

49. In June 2007, the Office of Inspector General of the Department of Health and Human Services ("OIG") published the results of a study it had conducted of the effect of basing FULs on AMP as required by the DRA. *See generally* Dep't of Health & Human Servs., Office of Inspector Gen., *Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program* 10 (June 2007) (OEI-03-06-00400), *available at* http://www.oig.hhs.gov/oei/reports/oei-03-06-00400.pdf. As part of that study, OIG concluded, "[b]ased on pricing and sales data provided by distributors," that for 19 of the 25 drugs studied (those with the highest Medicaid reimbursement in dollar terms), "average pharmacy acquisition costs would have been higher than the new Federal upper limit amounts." *Id.* at 11.

50. On July 17, 2007, CMS published a final rule implementing the FUL formula established by the DRA. Medicaid Program; Prescription Drugs, 72 Fed. Reg. 39,142 (July 17, 2007).

51. On November 7, 2007, the National Association of Chain Drug Stores ("NACDS") and the National Community Pharmacists Association ("NCPA") filed a complaint against the Department of Health and Human Services, the Secretary of the Department of Health and Human Services, CMS, and the Acting Administrator of CMS. *See generally* Complaint, *Nat'l Ass'n of Chain Drug Stores* v. *U.S. Dep't of Health & Human Servs.*, No. 07-cv-02017-RCL (D.D.C. Nov. 7, 2007) [Docket No. 1].

52. Citing the OIG and GAO studies as support, the complaint sought a declaration that the CMS regulation effectuating the DRA was illegal, a declaration that the public posting of

AMPs was illegal, and injunctions prohibiting CMS from implementing the regulation and publicly posting AMPs. *Id.* at 2-3, 16-17.

53. On December 17, 2007, the Court granted NACDS and NCPA's motion for a preliminary injunction and enjoined CMS from implementing the regulation effectuating the FUL formula established by the DRA. Order of December 17, 2007, *Nat'l Ass'n of Chain Drug Stores* v. *U.S. Dep't of Health & Human Servs.*, No. 07-cv-02017-RCL (D.D.C. Nov. 7, 2007) [Docket No. 36].

54. As part of the order granting the motion for preliminary injunctive relief, the Court found that implementation of the proposed regulation was "likely to cause Plaintiffs to suffer irreparable harm for which no adequate remedy at law exists as Plaintiffs' members will not be able to recover from the Defendants if the AMP Rule is implemented, and thousands of Plaintiffs' member pharmacies are expected to be forced to reduce hours and services, forced out of the Medicaid program, or forced to close." *Id.* at 1.

55. As part of the order granting the motion for preliminary injunctive relief, the Court found that "[i]ssuance of a preliminary injunction will serve the public interest as . . . Medicaid beneficiaries may find access to their retail community pharmacies reduced or eliminated should the injunction not be issued." *Id.* at 2.

56. On July 15, 2008, Congress enacted the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"), which provided that the pre-DRA FUL formula, which was 150% of the lowest published price, "shall continue to apply through September 30, 2009, for purposes of the availability of Federal financial participation for such payments," and which further stated that CMS "shall not, prior to October 1, 2009, finalize, implement, enforce, or otherwise take any action (through promulgation of regulation, issuance of regulatory guidance,

use of Federal payment audit procedures, or other administrative action, policy, or practice, including a Medical Assistance Manual transmittal or letter to State Medicaid directors) to impose the specific upper limit established under section 447.514(b) of title 42, Code of Federal Regulations as published on July 17, 2007." MIPPA, Pub. L. No. 110-275, § 203, 122 Stat. 2494 (2008); *see also* Congressional Research Serv., *P.L. 110-275: The Medicare Improvements for Patients and Providers Act of 2008*, at 29 (July 23, 2008) ("In the interim, FUL formulas remain calculated by CMS as equal to 150% of the published price for the least costly therapeutic equivalent.").

New York State and the FUL

57. Cesar A. Perales "served as the Commissioner of the New York Department of Social Services from January 1983 until November 1991," during which period "the New York Department of Social Services was responsible for, among other things, administering New York's Medicaid program." Affidavit of Cesar A. Perales, at ¶ 1 (hereinafter "Perales Aff.").

58. In 1986, Mr. Perales, on behalf of NYDSS, commented on the three alternative methods that HCFA was considering for setting upper limits for multisource and generic drug reimbursement. *Id.* at ¶ 2.

59. In his letter to HCFA, Mr. Perales stated that New York "is not in favor of the Pharmacists' Incentive Program" ("PhIP") – the proposal to base FULs on published prices, which HCFA ultimately adopted. *Id.* Ex. A, at 1.

60. In his letter, Mr. Perales stated that "the advertised price found in the Red Book or the Blue Book may not reflect the actual purchase price (APC)" and "the pharmacists' acquisition cost is likely to be lower than the price quoted in the Red or Blue Books." *Id.*

61. In his letter, Mr. Perales stated that under the PhIP program, "the Medicaid program may not realize savings in an appreciable amount since the markup of the acquisition costs will be significant." *Id.*

62. Mr. Perales' letter "reflects, among other things, New York Department of Social Services' understanding as of 1986 that a pharmacy's acquisition cost for a drug is likely to be lower than the prices quote[d] in third-party pricing compendia such as the Red Book or First DataBank." *Id.* at ¶ 3.

63. In 1994, the New York State Legislature amended the New York Social Services Law so as to require that "if [a] drug dispensed is a multiple source prescription drug for which an upper limit has been set by the federal health care financing administration," New York would reimburse providers for that drug at "an amount equal to the specific upper limit set by such federal agency for the multiple source prescription drug." N.Y. Soc. Serv. Law § 367-a(9)(b)(i) (McKinney 1994).

Harris Devor's Testimony and Report

64. When Mr. Devor was asked whether he agreed "that CMS doesn't always set the FUL on the basis of the lowest published price," he responded, "As I believe I said before, that I thought there were instances where they did not, I think I was aware of that." Excerpts of the Transcript of Deposition of Harris L. Devor at 62:8 – 62:15, attached to Nemirow Decl. as Ex. D.

65. During his deposition in this matter, when Mr. Devor was asked whether he had "computed what [he] believed the new FUL would have been if the Devor-estimated WACs and Devor-estimated AWPs were used to compute the FUL," he responded:

> A. Again, I'm just struggling a little bit with the "would have been." What I did was compute it assuming that those

> prices, the estimated WACs and AWPs that I computed, were used to compute the FUL at 150 percent of those prices.
>
> Q. What's the struggle with "would have been"?
>
> A. I may be incorrect, but I thought there was something in the way you asked the question that insinuated that the FUL would have been that, period. And I don't want to go to where—what CMS would have done with it. They may have chosen not to use it.
>
> Q. Because you just simply don't know what they would have done with it, right?
>
> MS. CICALA: Object to form.
>
> A. I didn't study what CMS would have done with it or not. I mean, I understand what—the way FULs are calculated, what CMS would have done in a hypothetical sense, given the fact that Barr in this case would have reported the Devor WACs or the Devor AWPs, I would only be speculating what CMS would do with it.

Id. at 468:7 – 469:14; *see also id.* at 457:16 – 457:18, 460:13 – 460:14, 469:15 – 469:17.

66. When Mr. Devor was asked about whether it was his "opinion that had the manufacturers reported the lower AWPs and WACs that [he had] calculated, that CMS would have used those lower AWPs and WACs to set FULs," as well as similar questions addressing the same issue, the following exchanges took place:

> A. That's not my opinion. I have no opinions on it. . . . That's beyond the scope of what I was asked to do and not really relevant to what I was asked to do. . . .
>
> Q. Is it your understanding that CMS always used the lowest published AWP or WAC?
>
> A. I know that's what the regulation itself says but I am not a hundred percent sure that they did that in all circumstances.

Id. at 57:1 – 58:18.

Q. Does your analysis consider how Barr's products, 58202 and 58210, could have impacted the FUL set by CMS after Barr discontinued those products?

MS. CICALA: Objection, beyond the scope.

A. My analysis was to determine based on the data given an average WAC and an—an estimated average WAC and an estimated average AWP for a 12-month period prior to that date which then could have been reported. It does not at all assume that that—that that would have impacted the ultimate FUL used or not, that's beyond the scope of what I was asked.

Id. at 516:8 – 516:21.

Q. Well, for this product, Par's WAC could not possibly have influenced the federal upper limit no matter what those WACs were, isn't that right?

A. Well, but, again, I have testified before, it is not within my knowledge range as to whether or not you know how CMS computed and how they should have computed a FUL. To the extent—so, I mean, that's my answer. It's beyond the scope of what I was asked to do. It does not impact—none of what you have asked me impacts my computation which is really the scope of my assignment.

Id. at 741:6 – 741:18.

Q. . . . [B]ecause your calculation was greater than the actual FUL, would you agree with me that for the periods in which you calculated a negative difference between the actual FUL and your estimated FUL, that Ivax's estimated AWP could not have impacted the FUL?

A. And as I have said before, that was beyond the scope of what I was asked to do. And I am not opining on how CMS actually computed its FUL or used the array of information.

Id. at 880:14 – 881:2.

67. Dr. Sumanth Addanki has found that Mr. Devor "has analyzed only about 13 percent of the NDCs in the relevant GCNs with published prices during the period at issue." *See* Addanki Aff., at ¶ 16.

68. Dr. Sumanth Addanki has found that "[f]or about 46 percent of the NDC-quarter combinations for which ***Mr. Devor's own exhibits*** report a published WAC and FUL, the ***published WAC*** was already low enough to have produced a lower FUL, had CMS used it." *Id.* at ¶ 17 & Ex. 6 (emphasis in original).

Respectfully submitted,

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On Behalf of All Defendants

Dated: May 15, 2009

CERTIFICATE OF SERVICE

I hereby certify that on May 15, 2009, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ Kim B. Nemirow
Kim B. Nemirow